PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Live lyophilisate and solvent for suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) contains:
Live bovine herpesvirus type 1, strain GK/D (gE^-): $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$

3. PACKAGE SIZE

5 doses
10 doses
25 doses
50 doses
100 doses
10 x 5 doses
10 x10 doses
10 x 25 doses
10 x 50 doses
10 x 100 doses

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use or intranasal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5095

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Glass Vial label – Lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Live 

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

BHV-1, strain GK/D (gE^-): $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$ per dose (2 ml)
5 doses
10 doses
25 doses
50 doses
100 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 hours.

5. ROUTE(S) OF ADMINISTRATION

Intramuscular use or intranasal use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE SOLVENT

Label of glass and PET vials - Solvent

1. NAME OF THE DILUENT/SOLVENT

Unisolve
Solvent for Bovilis IBR Marker Live

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml
50 ml
100 ml
200 ml

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C. Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Live lyophilisate and solvent for suspension for cattle

2. COMPOSITION

Each dose (2 ml) of reconstituted vaccine contains:

Live bovine herpesvirus type 1 (BHV-1), strain GK/D (gE^-)*: $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$**.

* gE^-: glycoprotein E negative
** $TCID_{50}$: tissue culture infective doses 50%

Lyophilisate: off-white to light pink-coloured pellet.
Solvent: colourless solution.

3. TARGET SPECIES

Cattle.

4. INDICATIONS FOR USE

Active immunisation of cattle to reduce the intensity and duration of the clinical respiratory signs induced by an infection with BHV-1 and to reduce nasal excretion of field virus.

Onset of immunity:
An increase in immunity was demonstrated 4 days after intranasal vaccination and 14 days after intramuscular vaccination of 3 month old seronegative animals.

Duration of immunity:
After intranasal administration to 2 week old calves immunity lasts at least until the age of 3-4 months. In the presence of maternally derived antibodies, the protection of the vaccine may not be complete until a second vaccination. This second vaccination should be administered at 3-4 months of age and will result in protective immunity that lasts for at least 6 months.
Single intranasal or intramuscular vaccination of 3 months old animals provides protective immunity (reduction of clinical signs and reduction of viral excretion), which was demonstrated via challenge 3 weeks after vaccination. Reduction of viral excretion is maintained for at least 6 months after single vaccination.
Revaccination to ensure protection after the initial 6 months protection period has elapsed will result in protective immunity that lasts for 1 year.

No information is available on the efficacy of the vaccine to prevent a latent wild virus infection or to prevent wild virus re-excretion in the latent carrier.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

The presence of maternal antibodies can influence the efficacy of the vaccination. Therefore, it is recommended to ascertain the immune status of calves before vaccination is started.

Special precautions for safe use in the target species:
After intranasal use, the vaccine virus can spread to in-contact cattle. Cattle which need to remain totally free from BHV-1 antibodies should be separated from intranasally vaccinated animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
No information is available on the use of this vaccine in breeding bulls.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data - in cattle from 3 weeks of age onwards - are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis Bovipast RSP.

Safety and efficacy data are available which demonstrate that for the intramuscular revaccination - in cattle from 15 months of age onwards (i.e. those that have previously been vaccinated separately with Bovilis IBR Marker Live and Bovilis BVD) - this vaccine can be mixed and administered with Bovilis BVD. The product literature of Bovilis BVD should be consulted before administration of the mixed products. The adverse effects observed after administration of one dose or an overdose of the mixed vaccines are not different from those described for the vaccines administered separately.

When mixed with Bovilis BVD at revaccination, the demonstrated efficacy claims for Bovilis IBR Marker Live are as follows:

- Active immunisation of cattle to reduce the fever induced by an infection with BHV-1 and to reduce nasal excretion of field virus.
- Duration of immunity: 12 months demonstrated by serological data.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.
Do not use together with immunosuppressive agents.

Overdose:
At a 10-fold overdose, no effects other than those described in section “Adverse events” have been observed.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product or with Bovilis BVD (for revaccination only).

7. ADVERSE EVENTS

Cattle:

Common (1 to 10 animals / 100 animals treated):	Elevated temperature[1], Nasal discharge[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] A rise of 1 °C may occur up to 5 days post vaccination.
[2] After intranasal vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Reconstitute the lyophilisate with the solvent:

Number of doses per vial	Volume (ml) of solvent needed
5	10
10	20
25	50
50	100
100	200

Dosage: a single dose of 2 ml reconstituted vaccine per animal.

Method of administration:
- from the age of 3 months onward: intranasal use or intramuscular use.
- at an age between 2 weeks and 3 months: intranasal use.

Primary vaccination:
- *Basic vaccination:*
Vaccinate each animal from 3 months of age onwards with one single dose.
- *Early protection schedule:*
When the first vaccination is given between the age of 2 weeks and 3 months, a second vaccination should be given at an age of 3-4 months.

First revaccination:
The first revaccination should be given 6 months after primary vaccination. Bovilis IBR Marker Inac can alternatively be used for this revaccination.

Subsequent revaccinations:
All following revaccinations should be given at an interval no greater than 12 months. Bovilis IBR Marker Inac can alternatively be used for these revaccinations.

The product literature of Bovilis IBR Marker Inac should be consulted before using it for revaccination.

For revaccination, the lyophilisate may be reconstituted shortly before use with Bovilis BVD for use in cattle from 15 months of age (i.e. those that have previously been vaccinated separately with Bovilis IBR Marker Live and Bovilis BVD). The following instructions should be used:

Bovilis IBR Marker Live		Bovilis BVD
5 doses	+	10 ml
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml

A single dose (2 ml) of Bovilis IBR Marker Live mixed with Bovilis BVD is given intramuscularly.

Shelf life after mixing with Bovilis BVD: 3 hours.

9. ADVICE ON CORRECT ADMINISTRATION

For intranasal use (1 ml in each nostril), the use of a nozzle is recommended.
Use sterile vaccination equipment free from disinfectants. To prevent the spread of any infective agents the intranasal equipment should be changed at each animal.

Visual appearance after reconstitution:
- In solvent: colourless to slightly opaque suspension.
- In Bovilis BVD: as specified in the product information for Bovilis BVD alone.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C if stored independently from the lyophilisate.
Do not freeze.

Shelf life after reconstitution according to directions: 3 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5095

Pack sizes:
Cardboard box with 1 glass vial of lyophilisate (5 doses) and 1 glass vial of solvent (10 ml).
Cardboard box with 1 glass vial of lyophilisate (10 doses) and 1 glass vial of solvent (20 ml).
Cardboard box with 1 glass vial of lyophilisate (25 doses) and 1 glass vial of solvent (50 ml).
Cardboard box with 1 glass vial of lyophilisate (50 doses) and 1 glass vial of solvent (100 ml).
Cardboard box with 1 glass vial of lyophilisate (50 doses) and 1 PET vial of solvent (100 ml).
Cardboard box with 1 glass vial of lyophilisate (100 doses) and 1 glass vial of solvent (200 ml).
Cardboard box with 10 glass vials of lyophilisate (5 doses) and a cardboard box with 10 glass vials of solvent (10 ml).
Cardboard box with 10 glass vials of lyophilisate (10 doses) and a cardboard box with 10 glass vials of solvent (20 ml).
Cardboard box with 10 glass vials of lyophilisate (25 doses) and a cardboard box with 10 glass vials of solvent (50 ml).
Cardboard box with 10 glass vials of lyophilisate (50 doses) and a cardboard box with 10 glass vials of solvent (100 ml).
Cardboard box with 10 glass vials of lyophilisate (50 doses) and a cardboard box with 10 PET vials of solvent (100 ml).
Cardboard box with 10 glass vials of lyophilisate (100 doses) and a cardboard box with 10 glass vials of solvent (200 ml).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

For animal treatment only.

The vaccine stimulates active immunity against bovine herpesvirus type 1 (BHV-1). The vaccine does not elicit antibodies to glycoprotein E of BHV-1 (marker vaccine). This enables discrimination between cattle vaccinated with this product and cattle infected with BHV-1 field virus or vaccinated with conventional non-marker BHV-1 vaccines.

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 24 September 2024